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U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:
MCMR-RMI-S (70-1y) 28 Aug 95

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for Phyllis Rinehart
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Deputy Chief of Staff
for Information Management

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MIPR NO: 92MM2556

TITLE: PHYSIOLOGICAL STUDY OF 4 MODIFIED SELF-CONTAINED VENTILATORS

SUBTITLE: Evaluation of the Impact 78G Self-Contained Ventilator

PRINCIPAL INVESTIGATOR: Peter H. Abbrecht, M.D., Ph.D.

CONTRACTING ORGANIZATION: Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
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PREPARED FOR: U.S. Army Medical Research and Development Command, Fort Detrick
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13. ABSTRACT *(Maximum 200 words)*

We evaluated the performance of four Impact model 780 self-contained ventilators before and after vibration testing. Units were tested using the internal compressor and external compressed air powered ventilation modes. We measured impedances to air flow of the input and output ports, the spontaneous inspiration circuit, and the C-2 air filter, and determined the ventilatory parameters including minute ventilation, tidal volume, mean delivered flow rate, insufflation time, exhalation time, and duty cycle. We also determined battery life under the different operating modes. There was relatively little difference in the ventilatory performance of the four different units. The only variable that changed significantly in response to vibration was insufflation time, with a corresponding change in duty cycle. In all four units, the exhalation ports leaked outward during insufflation. All filter connectors leaked unfiltered air inward during spontaneous inspiration and during powered ventilation with the compressor. The average resistance of the four units to inspiratory airflow during spontaneous breathing was 26.5 cm H_2O/(L/sec), a value that would probably make spontaneous inspiration through the ventilator impossible for a person with impaired pulmonary function.

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Evaluation of the Impact 780 Self Contained Ventilator

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The Impact 780 Self-Contained Ventilator consists of an electrically powered compressor, non-adjustable control circuitry, internal battery, external electrical power converter, air filter, hoses, and a multi-valve assembly to join the patient to the ventilator. The internal compressor draws in filtered ambient air and delivers it to the patient. High pressure fittings and a hose are provided to use compressed gas (50 to 80 psi) as an alternate form of powered ventilation. Electrical power is required for either type of powered ventilation, and can be supplied by the external power converter and battery, the external power converter alone, or the battery alone. The patient can always inspire filtered air in addition to, or in place of, either type of powered ventilation. Patient spontaneous inspiration does not require electrical power.

Four ventilators were tested at USUHS to determine the values of the mission critical clinical parameters, both before and after vibration challenge (IAW MIL-STD-810 Vibration, Method 514.3, Procedure X, XI), with three different sources of electrical power. The ventilators were evaluated using the internal compressor and external compressed gas powered ventilation modes. All compressed-gas ventilation testings were performed with compressed air. We also determined the flow/pressure relationships and compliance that would be experienced by a patient breathing spontaneously through the ventilator.

1. General Observations

The exhalation ports on all four patient valves (connector fitting between the patient and the ventilator tubing) leaked outward during powered ventilation insufflation. All filter connectors leaked unfiltered air inward during spontaneous inspiration and during powered ventilation with the internal compressor. In the latter case, from 111 to 765 ml/min of unfiltered air leaked past the filter into the system and was delivered to the patient valve. This leakage around the filter would also expose the patient to unfiltered air during spontaneous inspiration. We were able to eliminate the filter/connector leaks with gaskets. One of the units also had an outward leak inside the ventilator on the positive pressure side of the internal compressor circuit (419 ml/min) which reduced the amount of ventilation delivered to the patient.

The controls and hose fittings on the ventilator were so close together that they were difficult to use. One fuze blew inside a ventilator and another in a power converter. Just to validate the status of the fuzes required the use of tools to open the units resulting in exposure of their delicate internal components. The cause(s) of the blown fuzes was never discovered. Once the fuzes were replaced, there were no further occurrences of this problem.

The external compressed-gas circuit has a low pressure electronic alarm and warning light and a high pressure whistle. The low pressure alarm was active at an average value of 45 psi or less before the vibration challenge, and 47 psi after. The high pressure alarm turned on at an average of 89 psi before the vibration challenge, and 95 psi after. Once activated the high pressure alarm then turned off when the pressure was reduced to an average of 76 psi or less before the vibration challenge, and 84 psi after.

When operating with battery power, battery life was shorter in the internal compressor mode than when using external compressed gas. In the internal compressor mode starting with a fully charged battery, the average time to the first, intermittent low

battery alarm buzzer and light was 5.6 hours before the vibration challenge, and 4.8 hours after. The average time to continuous low battery alarm was 6.6 hours before the vibration challenge, and 6.8 hours after. Compressor action stopped completely after an average 7.2 hours operation before the vibration challenge, and 7.9 hours after.

The patient valve has a pressure relief valve to prevent exposing the patient to excessive pressures. The relief valve opened at an average pressure of 31 cm H_2O before the vibration challenge, and 28 cm H_2O after. Escaping flow through the relief valve sounded an alarm at an average pressure of 36 cm H_2O before the vibration challenge, and 35 cm H_2O after. For pressures between the opening level and the alarm level, gas was vented without any audible indication.

During powered ventilation, the maximum pressure that the patient might be exposed to is determined by the amount of flow delivered to the patient valve and by the characteristics of the pressure relief valve. With the internal compressor powered by the external power converter, the unit average peak pressure inside the patient valve was 46 cm H_2O before the vibration challenge and 43 cm H_2O after. With the internal compressor powered by just the internal battery, the average maximum pressure inside the patient valve was 44 cm H_2O before the vibration challenge and 41 cm H_2O after. Using 50 psi external compressed gas, the average maximum patient valve internal pressure was 42 cm H_2O before the vibration challenge and 40 cm H_2O after, and was only slightly influenced by choice of electrical power source.

2. Ventilator Impedance

The amount of ventilation delivered to the patient during powered ventilation depends on the ventilator circuit resistance, the patient's pulmonary resistance, and the amount of power (electrical or gas pressure) driving the ventilator. The following are average resistances at 1 L/sec flow rate measured before and after the vibration challenge.

	Resistance, cm $H_2O/(L/sec)$ ± SD	
Vibration Challenge State	Before	After
Patient Valve Components		
Powered Ventilation Input Port	231 ± 26	264 ± 37
Spontaneous Inspiration Input Port	6.8 ± 0.3	6.3 ± 0.4
Exhalation Output Port, without PEEP	7.5 ± 1.3	9.2 ± 2.5
Exhalation Output Port, with PEEP	19.5 ± 1.9	20.2 ± 2.0
Pressure Relief Valve	72.7 ± 2.6	79.3 ± 5.8
Entire Spontaneous Inspiration Circuit	26.3 ± 1.6	26.7 ± 1.8
Spontaneous Inspiration Hose	6.9 ± 0.5	7.4 ± 0.2
C-2 Air Filter	2.4 ± 0.1	2.4 ± 0.1

The average resistance (26.5 cm $H_2O/(L/sec)$) of the four units to inspiratory airflow during spontaneous breathing would probably make spontaneous inspiration through the ventilator impossible for a person with impaired pulmonary function.

To test the effects of increased patient impedance on ventilator performance, the systems were tested with seven different resistances at the patient interface port during powered ventilation using both the internal compressor and external compressed air. The following are the average tidal volumes during different powered ventilation modes for two extreme patient resistances.

	Tidal Volumes, L ± SD	
Added Resistance, cm H_2O/(L/sec)	0	50
Internal Compressor, Internal Battery and External Power Converter	0.96 ± 0.06	0.82 ± 0.03
Internal Compressor, Internal Battery	0.82 ± 0.04	0.74 ± 0.03
External Compressed Air at 50 psi Internal Battery and External Power Converter	0.77 ± 0.02	0.72 ± 0.02

3. Ventilator Capability

Compressed-Gas Ventilation

The effect of different inlet pressures on tidal volumes during compressed-air ventilation was determined. The following are the average tidal volumes for supplied inlet air pressures spanning the inlet pressure alarm limits.

	Tidal Volumes, L			
Inlet Pressure, psi	50	60	70	80
Tidal Volumes (liters)	0.76	0.90	1.03	1.18

Spontaneous-Inspiration Compliance

The spontaneous inspiration circuit average static compliance was almost constant for a range of vacuums up to -25 cm H_2O. The average compliance was 0.41 ml/cm H_2O before the vibration challenge and 0.46 ml/cm H_2O after.

Powered Ventilation Performance

The following tables summarize the powered ventilation results for each of the two powered ventilation modes (internal compressor and external compressed air at 50 psi). Each ventilation mode was tested with three difference sources of electrical power (external power converter and battery, external power converter alone, and battery alone). For each ventilation mode and power source, 10 measurements were made on each of the four units. Thus, the mean values are the average of 40 measures (ten replications of each of the four units).

Powered Ventilation Mode: Internal Compressor
Electrical Power Source: External Power Converter and Battery

Before Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	15.48	0.90	0.14
Tidal Volume,	L	0.978	0.054	0.008
Mean Delivered Flow Rate,	L/sec	0.571	0.034	0.005
Frequency,	1/min	15.83	0.32	0.05
Duty Cycle,	%	45.18	1.07	0.17
Insufflation Time,	sec	1.713	0.048	0.008
Expiration Time,	sec	2.078	0.064	0.010

After Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	15.07	0.86	0.14
Tidal Volume,	L	0.959	0.054	0.009
Mean Delivered Flow Rate,	L/sec	0.550	0.029	0.005
Frequency,	1/min	15.72	0.19	0.03
Duty Cycle,	%	45.72	0.68	0.11
Insufflation Time,	sec	1.746	0.031	0.005
Expiration Time,	sec	2.074	0.039	0.006

Powered Ventilation Mode: Internal Compressor
Electrical Power Source: External Power Converter

Before Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	15.15	0.92	0.15
Tidal Volume,	L	0.960	0.056	0.009
Mean Delivered Flow Rate,	L/sec	0.561	0.037	0.006
Frequency,	1/min	15.79	0.34	0.05
Duty Cycle,	%	45.03	1.00	0.16
Insufflation Time,	sec	1.712	0.058	0.009
Expiration Time,	sec	2.090	0.052	0.008

After Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	14.71	0.74	0.12
Tidal Volume,	L	0.939	0.048	0.008
Mean Delivered Flow Rate,	L/sec	0.537	0.026	0.004
Frequency,	1/min	15.67	0.21	0.03
Duty Cycle,	%	45.74	0.72	0.12
Insufflation Time,	sec	1.752	0.033	0.005
Expiration Time,	sec	2.079	0.042	0.007

Powered Ventilation Mode: Internal Compressor
Electrical Power Source: Battery

Before Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.89	0.73	0.12
Tidal Volume,	L	0.824	0.046	0.007
Mean Delivered Flow Rate,	L/sec	0.483	0.024	0.004
Frequency,	1/min	15.64	0.24	0.04
Duty Cycle,	%	44.55	1.13	0.18
Insufflation Time,	sec	1.710	0.045	0.007
Expiration Time,	sec	2.128	0.060	0.009

After Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.78	0.56	0.09
Tidal Volume,	L	0.817	0.036	0.006
Mean Delivered Flow Rate,	L/sec	0.473	0.019	0.003
Frequency,	1/min	15.64	0.23	0.04
Duty Cycle,	%	45.02	0.85	0.13
Insufflation Time,	sec	1.727	0.041	0.006
Expiration Time,	sec	2.110	0.046	0.007

Powered Ventilation Mode: External Compressed-Air (50 psi at inlet during flow)
Electrical Power Source: External Power Converter and Battery

Before Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.21	0.49	0.08
Tidal Volume,	L	0.767	0.015	0.002
Mean Delivered Flow Rate,	L/sec	0.494	0.016	0.002
Frequency,	1/min	15.91	0.44	0.07
Duty Cycle,	%	41.22	0.79	0.13
Insufflation Time,	sec	1.555	0.034	0.005
Expiration Time,	sec	2.220	0.081	0.013

After Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.18	0.37	0.06
Tidal Volume,	L	0.775	0.021	0.003
Mean Delivered Flow Rate,	L/sec	0.495	0.018	0.003
Frequency,	1/min	15.72	0.20	0.03
Duty Cycle,	%	40.97	0.64	0.10
Insufflation Time,	sec	1.565	0.030	0.005
Expiration Time,	sec	2.255	0.039	0.006

Powered Ventilation Mode: External Compressed-Air (50 psi at inlet during flow)
Electrical Power Source: External Power Converter

Before Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.12	0.39	0.06
Tidal Volume,	L	0.767	0.015	0.002
Mean Delivered Flow Rate,	L/sec	0.493	0.017	0.003
Frequency,	1/min	15.81	0.31	0.05
Duty Cycle,	%	40.95	0.77	0.12
Insufflation Time,	sec	1.555	0.042	0.007
Expiration Time,	sec	2.243	0.052	0.008

After Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.21	0.35	0.06
Tidal Volume,	L	0.778	0.020	0.003
Mean Delivered Flow Rate,	L/sec	0.497	0.017	0.003
Frequency,	1/min	15.68	0.20	0.03
Duty Cycle,	%	40.94	0.58	0.09
Insufflation Time,	sec	1.567	0.031	0.005
Expiration Time,	sec	2.261	0.035	0.006

Powered Ventilation Mode: External Compressed-Air (50 psi at inlet during flow)
Electrical Power Source: Battery

Before Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.04	0.37	0.06
Tidal Volume,	L	0.767	0.0014	0.002
Mean Delivered Flow Rate,	L/sec	0.491	0.014	0.002
Frequency,	1/min	15.69	0.31	0.05
Duty Cycle,	%	40.91	0.93	0.15
Insufflation Time,	sec	1.566	0.039	0.006
Expiration Time,	sec	2.262	0.064	0.010

After Vibration Challenge

Ventilation Variables	(units)	Mean	Std Dev	Std Error
Minute Ventilation,	L/min	12.24	0.38	0.06
Tidal Volume,	L	0.781	0.022	0.003
Mean Delivered Flow Rate,	L/sec	0.498	0.017	0.003
Frequency,	1/min	15.67	0.22	0.04
Duty Cycle,	%	40.97	0.53	0.08
Insufflation Time,	sec	1.568	0.029	0.005
Expiration Time,	sec	2.261	0.038	0.006

The compressor motor used during internal compressor ventilation requires much more power from the battery than does the solenoid during external compressed-gas ventilation. The internal compressor produces a higher flow rate when supplied by the external power converter than when supplied by just the internal battery. Therefore, the internal compressor mode has larger variability for the minute ventilation, tidal volume, and mean delivered flow rate as a function of electrical power source than does the external compressed-gas mode.

The p values of the main effects from the analyses of variance are also listed. The analysis assessed the main effects and their interactions of three independent factors. These factors were: the units, the vibration challenge (VIB), and the sources of electrical power. There were 4 units of the same design. There were two VIB states: before and after. There were three different sources of electrical power: external electrical power converter and battery, external electrical power converter alone, and battery alone. The ten replicated measures were treated as nested terms. We chose p values less than or equal to 0.05 as statistically significant, and they are indicated in bold print.

The following is a listing of p values of the main effects from an analysis of variance for each dependent ventilation variable and each ventilation mode. Each analysis included ten replications for each repeated measure of four units, before and after the vibration challenge, using the three different electric power sources.

	p Values					
	Internal Compressor			External Compressed Air		
	Unit	VIB	Power	Unit	VIB	Power
Minute Ventilation,	**0.0001**	0.1133	**0.0001**	**0.0001**	0.6748	**0.0027**
Tidal Volume,	**0.0001**	0.2068	**0.0001**	**0.0001**	0.3516	0.1258
Mean Delivered Flow Rate,	**0.0001**	0.0539	**0.0001**	**0.0001**	0.5942	0.5605
Frequency,	**0.0001**	0.1331	**0.0008**	**0.0001**	0.1676	**0.0017**
Duty Cycle,	**0.0001**	**0.0367**	**0.0045**	**0.0001**	0.5780	0.1768
Insufflation Time,	**0.0001**	**0.0100**	0.0748	**0.0001**	0.0632	0.1183
Expiration Time,	**0.0001**	0.3571	**0.0007**	**0.0001**	0.2651	**0.0045**

While there were many statistically significant differences for the various ventilation variables, the differences may not be functionally significant especially because the variation in ventilation requirements of different sized patients may markedly exceed the small differences in ventilator performance observed in these tests.